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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/892,206 | 06/26/2001 | Thomas J. Brennan | R-171 | 9330 |

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DELTAGEN, INC.
1003 Hamilton Avenue
Menlo Park, CA 94025

| EXAMINER | |
|----------------------|--------------|
| BERTOGGIO, VALARIE E | |
| ART UNIT | PAPER NUMBER |
| 1632 | |

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

Application No.

09/892,206

Applicant(s)

BRENNAN ET AL.

Examiner

Valarie Bertoglio

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-37, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-37, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 02/09/2004 has been entered. Claims 38-40 have been cancelled. Claims 34 and 41 have been amended. Claims 34-37, 41 and 42 are pending and under consideration in the instant action.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-36, 41 and 42 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. The rejection is maintained for reasons of record set forth on pages 2-5 of the previous office action mailed 11/05/2003.

The claims are directed to a transgenic mouse whose genome comprises a disruption in the endogenous mouse anaphylatoxin C3a receptor gene, and wherein the mouse exhibits relative to wild-type, reduced thymus weight, reduced thymus size, or reduced thymus to body weight ratio. The claims are further directed to cells and tissues isolated from the same mouse.

Applicant argues that the claimed mice exhibit, relative to wild-type, reduced thymus weight, reduced thymus size, or reduced thymus to body weight ratio are useful in screening for

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agents that are capable of affecting phenotypic characteristics of the thymus (refer to page 5, lines 9-12).

In response, this argument is not persuasive. Screening for agents that affect characteristics of the thymus is not a substantial or well-established utility (see pages 2-5 of the previous office action mailed 11/05/2003). The evidence of record fails to correlate the reduced thymus weight, reduced thymus size, or reduced thymus to body weight ratio to any disease. While the specification has purported that the nucleotide sequence set forth in SEQ ID NO:1 encodes an anaphylatoxin C3a gene, the evidence of record has failed to provide a correlation between an anaphylatoxin C3a gene, the phenotypes of reduced thymus weight, reduced thymus size, or reduced thymus to body weight ratio and any disease or disorder. The specification has merely provided general assertions that the claimed transgenic mice may be used to identify agents that affect a phenotype related to the mice. As such, without a correlation between an anaphylatoxin C3a gene, the above-mentioned thymus phenotypes and a disease or disorder, it appears there would be no well-established or substantial utility for an agent identified through such a screening procedure. Therefore, there is no well-established or substantial utility for the claimed mice.

Claims 34-37, 41 and 42 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following issue of enablement must also be addressed:

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Claim 42 encompasses transgenic mice comprising a heterozygous disruption in the endogenous mouse anaphylatoxin C3a receptor gene wherein said mouse does not exhibit a phenotype. The rejection of claim 42 based on the failure of the specification to enable one of skill in the art to use the claimed heterozygous mouse is maintained for reasons of record set forth on pages 6-7 of the previous office action mailed 11/04/2003.

Applicant argues that the claims now relate to a transgenic mouse whose genome comprises a homozygous disruption in the anaphylatoxin C3a receptor gene.

As set forth in the previous office action (refer to Leonard and Griffiths), the phenotype of knockout mice is unpredictable. The specification asserts that the claimed mice can be used for identifying agents that modulate a phenotype exhibited by the mice (pages 19-20). However, the specification fails to describe any phenotype exhibited by a heterozygous mouse embraced by the claims. The skilled artisan would not know how to use a transgenic knockout mouse that lacks a phenotype, particularly because the instant specification has not provided uses for such.

Furthermore, claim 42 continues to encompass both homozygous and heterozygous mice. The phenotypic limitation of the homozygous mouse in parent claim 41 does not limit the mouse made by the methods of claim 41 to a homozygous mouse and therefore, the mouse of claim 42 is not limited to a homozygous mouse. Therefore, claim 42 encompasses heterozygous mice without a phenotype, which, as set forth on pages 6-7 of the previous office action mailed 11/05/2003 is not enabled by the instant specification.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PETER PARAS, JR.
PRIMARY EXAMINER



Valarie Bertoglio
Examiner
Art Unit 1632